ELITE PHARMACEUTICALS INC /DE/
Form 8-K
September 01, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

August 27, 2010

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-15697	22-3542636
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

165 Ludlow Avenue, Northvale, New Jersey 07647

(Address of principal executive offices)

(201) 750-2646

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry Into A Material Definitive Agreement.

On August 27, 2010, Elite Pharmaceuticals Inc. ("Elite") executed an agreement with Mikah Pharma, LLC ("Mikah") to undertake and perform development work to facilitate the preparation of a regulatory filing for a product under development (the "Product Development Agreement"). The product will be formulated with a previously approved drug substance and will be designed to be delivered in a unique delivery profile. Among other responsibilities, Elite will provide formulation, analytical development, clinical batch manufacture and validation work for the product. The parties agreed that, in lieu of cash, the transfer to Elite of the Naltrexone product in accordance with the terms of the Naltrexone Asset Purchase Agreement (see discussion at Item 2.01 below), which they valued at $200,000, constituted the consideration for the development services being performed by Elite under the Product Development Agreement. Mikah will also pay to Elite, on a quarterly basis, a royalty in the amount of 5% of net sales of the product. The royalty will be due and payable for the duration of the period beginning on the date that the product is approved by the United States Food and Drug Administration (the "FDA") and ending on the date of the introduction into the market of an equivalent generic product. Upon approval of the new drug application by the FDA, Elite will manufacture the product and the parties will negotiate in good faith a manufacturing and supply agreement for the product. The Product Development Agreement has a term of 10 years. One year prior to the termination date, the parties will meet to discuss the commercial options relating to the supply and distribution of the product after the termination date. There is no guarantee that the product will receive approval from the FDA.

Item 2.01 Completion of Acquisition or Disposition of Assets.

On August 27, 2010, Elite executed the Naltrexone Asset Purchase Agreement with Mikah pursuant to which Elite acquired from Mikah the Abbreviated New Drug Application number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto (the "ANDA"), that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in the ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of $200,000. In lieu of cash, Mikah agreed to accept from Elite product development services to be performed by Elite, as described in Item 1.02 above. Elite has assumed and agreed to discharge certain liabilities related to the purchased assets, including but not limited to liabilities arising from any infringement claim, product liability claim or liabilities arising from an action by the FDA or any other governmental entity, so long as any such liability occurs after the date of acquisition. Elite granted to Mikah and its affiliates a fully-paid, perpetual, royalty-free non-exclusive license to use the ANDA in connection with the manufacture, registration or sale of the products outside of the United States and its territories.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits
99.1 Press Release dated September 1, 2010.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 1, 2010

ELITE PHARMACEUTICALS, INC.

By: /s/ Chris Dick
Name: Chris Dick

Title: President & Chief Operating Officer